

## RESPONSE

The claims of the present application have been amended to limit the claimed invention to chewing gum compositions and corresponding methods of use in which the stain removing components are selected from a peroxide compound and an anionic surfactant. Accordingly, claims 3-8, 23, 25, and 35, all including reference to polyphosphate compounds, have been cancelled. Applicants reserve the right to pursue polyphosphate as a stain removing component in a continuation application.

Accordingly, the present invention is directed to a chewing gum composition in which two stain removing components are employed, a peroxide compound and an anionic surfactant. The stain removing components must not be materially bound to the gum base in order to provide a stain removing effect.

Page 2 of the Office Action rejects claims 1-8, 20-23, 29, 33, 39, 40, 42, and 43 as obvious over the combination of Day (WO 01/39606) in view of Sagel (U.S. Patent No. 6,582,708). The Office Action states that Day teaches encapsulating or adding the polyphosphate to the coating of the disclosed chewing gum that Sagel discloses that the stability of whitening agents is improved when they are encapsulated. The Office Action concludes that the rejected claims are obvious based on the combination of these references. The rejection is hereby traversed and reconsideration is respectfully requested.

As previously indicated, the present invention employs the combination of stain removing agents of a peroxide compound and an anionic surfactant. Day requires the presence of a polymeric surface active agent such as polyphosphate. The presence of polyphosphate is a necessary part of the Day disclosure because the prior art chewing gum composition will provide surface conditioning effects on a subject's teeth and/or oral mucosa (page 2, line 37- page 3, line 1).

Day mentions at page 3, line 30 that whitening agents may be among the "carrier materials" that may be incorporated in the chewing gum composition. Page 6, line 35 states again that additional chewing gum components include carrier materials. However, there is no further mention of whitening agents in the reference. Instead, mention is made of softeners including sodium stearate and potassium stearate, which are specifically incorporated into the gum base to enhance chewability of the chewing gum composition (page 8, lines 22-34).

Thus, Day differs from the present invention in that it requires a polymeric surface active agent (polyphosphate) and makes no mention of peroxides or surfactants as stain removing agents. Instead, surfactants are used as softeners and purposely incorporated into the gum base.

Applicants' claims require that the stain removing components are not materially bound to the gum base. The disclosure that surfactants are purposefully incorporated into the gum base is a teaching away from the present invention.

Sagel discloses a tooth whitening substance which comprises a high concentration of water, a peroxide, a gelling agent and carrier materials (abstract). Peroxide is known to be unstable in the presence of water. The reference indicates that to improve stability of a peroxide, it was known in the art to encapsulate the peroxide. However, Sagel discloses another way of stabilizing peroxide, that is by placing the peroxide in a thin layer, having a high surface area to volume form (column 2, lines 1-10).

Thus, Sagel is directed to a tooth whitening substance where peroxide is the active agent which must be placed in a thin film delivery system. There is no teaching or suggestion of how to incorporate peroxide into a chewing gum composition alone and specifically in combination with an anionic surfactant so that both may be released upon chewing to perform a stain removing function. There are significant differences in structure and methodology between thin film strips which are placed upon the teeth and not chewed and chewing gum compositions which must be capable of releasing the stain removing agents.

The combination of Day and Sagel does not teach or suggest the claimed invention. Sagel is concerned with thin film strips. One of ordinary skill in the art would

not look to this reference to identify or solve problems of incorporating stain removing agents and particularly a peroxide and an anionic surfactant into a chewing gum. Day is principally focused on the use of a polymeric surface active agent in the form of a polyphosphate which has been eliminated from the present claims for purposes of prosecution in the present application. The combination of these references cannot lead one of ordinary skill in the art to the presently claimed invention.

Claims 1, 3-8, 33, 39, 42, 43, and 44-46 stand rejected over the combination of Day and Cherukuri (U.S. Patent No. 4,980,178). The rejection is hereby traversed and reconsideration is respectfully requested.

In connection with this rejection, it is noted that the claims that would specifically refer to anionic surfactants alone or in combination with peroxide have not been rejected over this combination of references. More specifically, claims 9-14, all specifically referring to anionic surfactants have not been rejected. Similarly, claims 20-25 have not been rejected (note that claims 23 and 25 have been cancelled because they refer to polyphosphate). On this basis alone, it is submitted that the combination of Day and Cherukuri is insufficient to reject the claims as amended and withdrawal of the rejection is respectfully requested. It is further noted that Cherukuri discloses anionic surfactants [e.g. acetylated monoglycerides (column 5, lines 40-42) and sodium stearate (column 6, line 51)] as plasticizing or softening agents incorporated directly into the gum base where they cannot effectively function as stain removing agents.

Claims 1, 3-10, 13, 14, 25, 33, 35, 39, 40, 42, and 43 stand rejected as obvious over the combination of Day in view of Chaykin (U.S. Patent No. 6,013,274) further in view of Witzel (U.S. Patent No. 4,238,475).

Day is stated to disclose chewing gum compositions including polyphosphate. Mention is made of additional agents including whitening agents, such as peroxides and surfactants at page 11, lines 27-30. This paragraph merely mentions that whitening agents such as peroxide or percarbonate and surfactants may be added to the chewing gum composition. There is no teaching or suggestion in the reference of how to effectively incorporate the whitening agents into a chewing gum so that they can effectively be released to perform a stain removing function. Furthermore, Day requires a polymeric surface active agent which is excluded from the present claims as a stain removing agent.

Chaykin is stated to disclose oral compositions such as chewing gums that reduce plaque and calculus deposition. This is not what Chaykin discloses. Column 1, lines 34-40 provide background to the Chaykin disclosure by indicating that limited scope methods and compositions have previously been used in an attempt to achieve good oral hygiene. These limited scope methods "are inconvenient" because they require devices ranging from toothbrushes to...gums. Chaykin instead creates an edible oral cleansing and sanitizing composition that contains three classes of cleansing and sanitizing agents, namely surfactants, sequestrants (chelators), and protein flocculators (column 2, lines 11-21 and 41-46). As indicated beginning at column 2, line

49, the reference composition permits a bypassing of the equipment requirement of traditional oral sanitizers. All the user needs to do is swallow (i.e. the formulations are ingestible and palatable). Chewing gum compositions are not to be swallowed and therefore it is clear that Chaykin does not teach or describe a chewing gum composition nor recognize the problems of delivering stain removing agents from a composition containing a hydrophobic gum base.

The combination of Day and Chaykin therefore does not solve the problem of how to deliver stain removing agents from a chewing gum composition. Instead, Chaykin teaches you must eliminate chewing gum as a delivery vehicle.

Witzel is directed to a chewing gum composition which is capable of delivering therapeutic agents to the oral cavity as described at column 3, lines 20-28. None of the active agents referred to therein are peroxides or surfactants, nor is any stain removing agent disclosed. Witzel therefore does not provide any teaching that would complement the primary references to solve the problem of incorporating peroxides and anionic surfactants as stain removing agents in a chewing gum composition where the presence of hydrophobic gum base must be addressed in order to get effective release of the stain removing agent.

Claims 11 and 12 stand rejected as unpatentable over Day, in view of Chaykin, in view of Witzel and further in view of Kleber (U.S. Patent No. 5,064,640). Kleber is

stated to use sodium stearate as an anionic surfactant in oral compositions. The rejection is hereby traversed and reconsideration is respectfully requested.

Applicants do not dispute that sodium stearate is an anionic surfactant. However, anionic surfactants have been used in chewing gum compositions containing hydrophobic gum base as a plasticizer or softening agent for the gum base to make it more chewable. As a result, it is purposefully incorporated into the gum base to achieve this benefit.

Kleber disclose an anti-cariogenic aluminum-containing emulsion in which the emulsion is stabilized with a surfactant. Thus, the surfactant is tied up in the emulsion wherein the active agent is the aluminum as best described at column 2, lines 64 - column 3, line 5. There is no indication that the surfactant provides a stain removing effect when bound up in an emulsion containing an active agent such as aluminum. Accordingly, Kleber does not add any meaningful disclosure to the primary references.

Claims 1, 2, 9, 10, 13, 14, 20-22, 24, 29, 30, 33, 39, 42, and 43 stand rejected as obvious over Chaykin, in view of Witzel, and further in view of Sagel. The rejection is hereby traversed and reconsideration is respectfully requested.

The aforementioned rejection relies principally on Chaykin which, as previously indicated, does not teach chewing gum compositions. In fact, the reference counsels against chewing gum compositions because of the reasons presented in column 1, lines

31-39. When the principal reference teaches against chewing gum compositions, references which may disclose chewing gum compositions cannot be used to render obvious a chewing gum composition which employs two stain removing agents (peroxide and anionic surfactant) wherein the stain removing agents must be incorporated into the chewing gum composition in a manner which enables effective release (i.e. not materially bound to the gum base).

Sagel likewise does not disclose chewing gum compositions as an effective delivery vehicle. Instead, Sagel makes it clear that in order to stabilize a peroxide component, you must place the peroxide in a thin film strip which is an entirely different product than a chewing gum composition. Thus, two of the references involved in this rejection teach away from chewing gum compositions and therefore the rejection cannot be sustained.

Finally, Applicants note the Examiner's Response in connection with the previously discussed comparative data showing unexpected results. The Examiner acknowledges that the results are more than additive. Thus, the requirement of an unexpected result (i.e. non-obviousness) has been met. However, the Examiner indicates that the test results are not commensurate in scope with the claims. However, there is no reasoning offered as to why other surfactants and peroxide would not be expected to yield the same or similar results. Applicants therefore submit that the results submitted are good enough, and complete enough, to support the present claims as amended.



In view of the forgoing, Applicants submit that the present Application is in condition for allowance, and early passage to issue is therefore deemed proper and is respectfully requested.

Respectfully submitted,



Allen R. Kipnes, Esquire  
Registration No. 28,433  
Attorney for Applicant

Address All Correspondence to:

Allen R. Kipnes, Esquire  
WATOV & KIPNES, P.C.  
P.O. Box 247  
Princeton Junction, NJ 08550  
(609) 243-0330